4/2/99

K990749

X-TECH® MEDICAL

510(k) Summary

Date of Application: March 4, 1999

Applicant: X-TECH® Medical
111 Wild Oak Court
Danville, CA 94506
Contact Person: Edgar A. Rainin, MD, President
Phone: 925-736-5001
Fax: 925-736-8315

1. TRADE NAME: SOF-SUCTION™ FLUID EVACUATION SYSTEM

2. COMMON NAMES: eye spears, sponge points & suction tubing

3. CLASSIFICATION NAME: sponge, ophthalmic & tube, aspirating, flexible, connecting

4. EQUIVALENT TO: Merocel Sponge Points and Datex-Ohmeda Suction Tubing.

5. DESCRIPTION OF DEVICE: Consists of a proximal portion consisting of a 11 mm x 7 mm x 7 mm polyvinyl acetal sponge tip fastened by heat bonding to a 7 mm 18Ga thin wall 301 stainless steel cannula friction attached to a 36" 5 Fr polyvinyl acetate suction tubing, attached with medical grade adhesive to a ¼" standard suction tubing adapter. Included with the device is adhesive tape for fixating the suction tubing.

6. INTENDED USE: The device is used to continuously wick away irrigation fluid during eye surgery in an atraumatic manner since the suction does not reach the delicate tissues of the eye. The device can also be used in neurosurgery and other surgeries that cannot tolerate direct suction on tissue.

7. TECHNOLOGICAL CHARACTERISTICS: Our device consists of a combination of the Merocel Sponge Point and Suction Tubing. This results in continuous wicking by the sponge since the sponge is continuously emptied at its distal reservoir by aspirating the fluid from the reservoir. We are introducing no new materials. We are simply combining two proven technologies in a new, safe and effective manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1999

Edgar A. Rainin, MD
President
X-TECH®MEDICAL
111 Wild Oak Court
Danville, CA 94506

Re: K990749
Trade Name: Sof-Suction Fluid Evacuation System
Regulatory Class: II
Product Code: 86 HOZ
Dated: March 4, 1999
Received: March 8, 1999

Dear Dr. Rainin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K 990749

Device Name: Sof-Suction™ Fluid Evacuation System

Indications For Use:

The Sof-Suction™ Fluid Evacuation System is used to remove excess irrigation fluids from the medial canthus of the eye during microscopic eye surgery to mitigate the effects of disturbing reflections from the fluid surface and to prevent stagnant irrigating fluid from entering the eye

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, PH.D

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 990749

Prescription Use ✓
(Per 21 CFR 801.109).